

### **REMARKS**

Applicant respectfully requests entry of the amendments and remarks submitted herein. Claims 1-5, 10-11, 16-18, 20, 22-23, 32, and 44 are amended; claims 6-9, 26-31 and 33-52 are canceled; and claim 53 is added. Therefore, claims 1-5, 10-25, 32 and 53 are currently pending, with claims 24-25 withdrawn from consideration.

#### **35 U.S.C. § 112, Second Paragraph**

Claims 7-9, 17-18 and 20 were rejected under 35 U.S.C § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention.

The Examiner states that concerning claims 7-9, the defining of the flavor intensity is indefinite because it is relative. Applicant respectfully disagrees with the Examiner's statement. In order to expedite prosecution of the application, however, Applicant has cancelled claims 7-9.

The Examiner states that concerning claim 17, it is not clear if applicant intends for a Markush group; if so, the proper language is "selected from the group consisting of." The Examiner states that claim 20 has the same problem as claim 17. Claims 17 and 20 have been amended to recite the language suggested by the Examiner.

The Examiner states that concerning claim 18, it is not clear if applicant intends for a Markush group; if so, the proper language is "selected from the group consisting of." Claim 18 has been amended to recite the language suggested by the Examiner.

The Examiner further states that the term "bakery mixes" is indefinite because it is not known what type of food is encompassed in the term. Applicant asserts that one of ordinary skill in the art would be aware of the customary usage of the term "bakery mixes." In order to expedite prosecution of the application, however, Applicant has deleted the term "bakery mixes" from the pending claims.

Applicant, therefore, respectfully asserts that these rejections under 35 U.S.C § 112, second paragraph should be withdrawn.

#### **35 U.S.C. § 102(b) – Wang et al.**

The Examiner has rejected claims 1-15 and 32 under 35 U.S.C. § 102(b) as anticipated by Wang et al. (5,512,287).

Claim 1 recites a dietary fiber composition isolated from a cereal grain containing  $\beta$ -glucan, comprising: a  $\beta$ -glucan composition having a weight average molecular weight ranging from about 50 kDa to about 250 kDa, wherein a 1% mixture by weight of said dietary fiber composition and water is stable and has a viscosity of about 1500 cps or less, and wherein the dietary fiber containing material has a neutral, non-lubricious mouthfeel. Claims 2-15 depend either directly or indirectly from claim 1.

Claim 32 recites a composition, comprising: a  $\beta$ -glucan composition in amount sufficient to lower LDL-C, wherein said  $\beta$ -glucan composition comprises a  $\beta$ -glucan compound having a weight average molecular weight less than or equal to about 200 kDa, and wherein said  $\beta$ -glucan composition has a viscosity less than or equal to about 100 cps, and a 1% mixture by weight of said dietary fiber composition and water is stable and has a viscosity of about 1500 cps or less, and wherein the dietary fiber containing material has a neutral, non-lubricious mouthfeel.

35 U.S.C. § 102(b) provides that "a person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States. . ." As discussed above, anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration, and there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art.

Wang et al. disclose a method of recovering naturally-occurring  $\beta$ -glucan from cereal grains (abstract). The recovered  $\beta$ -glucan has significant viscosity (col. 2, lines 30-33). The naturally-occurring  $\beta$ -glucan of cereal grains range in size from 500 kDa to 3000 kDa (col. 2, lines 49-51). The product of the Wang et al. method contains  $\beta$ -glucan ranging from about 400 kDa to about 2000 kDa (col. 2, lines 62-65). Wang et al. do not teach or suggest a  $\beta$ -glucan having the claimed molecular weight range, namely, a weight average molecular weight ranging from about 50 kDa to about 250 kDa, as recited by claims 1-15, or having a weight average molecular weight less than or equal to about 200 kDa, as recited by claim 32. Therefore, the claims are not anticipated by Wang et al.

Applicant respectfully asserts that this rejection under 35 U.S.C. § 102(b) should be withdrawn.

**35 U.S.C. § 103(a) – Wang et al.**

The Examiner has rejected claims 1-15 and 32 under 35 U.S.C. § 103(a) as obvious over Wang et al. (5,512,287).

Claims 1-15 and 32 are described above.

As reiterated by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), the framework for the objective analysis of determining obviousness under 35 U.S.C. § 103(a) is stated in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The factual analysis involves (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, and (3) resolving the level of ordinary skill in the pertinent art. Cited documents must be considered in their entirety, and it is not permissible to pick and choose from any one document only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such document fairly suggests to one of ordinary skill in the art (*see, e.g., Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 U.S.P.Q. 416 (Fed. Cir. 1986) and *In re Wesslau*, 353 F.2d 238, U.S.P.Q. 391 (C.C.P.A. 1965)).

Wang et al. disclose that naturally-occurring  $\beta$ -glucan from cereal grains range in size from 500 kDa to 3000 kDa. This range is well outside the claimed range of about 50 kDa to about 250 kDa (as recited by claims 1-15) or less than or equal to about 200 kDa (as recited by claim 32). Since Wang et al. was recovering naturally-occurring  $\beta$ -glucan from cereal grains, and they teach that naturally-occurring  $\beta$ -glucan from cereal grains are larger than 500 kDa, there is a distinct difference between what is taught by the cited reference, and the claims at issue. Also, one of skill in the art would not be motivated to modify the Wang et al. method to modify  $\beta$ -glucan because that would be completely contradictory of the goal of obtaining naturally-occurring  $\beta$ -glucan. Further, since one of the objective and advantages of the Wang et al. product was that the  $\beta$ -glucan developed "significant viscosity" (col. 2, lines 30-34), one would not have been motivated to generate shorter  $\beta$ -glucan molecules that would have a low viscosity. Moreover, Wang et al. teach away from enzymatic digestion of the naturally-occurring  $\beta$ -glucan

when they teach "heating the resulting liquid phase to destroy  $\beta$ -glucanase activity" (claim 1). Therefore, the claims are patentable over Wang et al.

Applicant respectfully asserts that this rejection under 35 U.S.C. § 103(a) should be withdrawn.

**35 U.S.C. § 103(a) – Wang et al. in view of Smith**

The Examiner rejected claims 16-23 under 35 U.S.C. § 103(a) as obvious over Wang et al. (5,512,287) in view of Smith (5,458,893).

Claim 16 recites a dietary fiber composition according to claim 1, wherein the composition is incorporated into a food product. Claims 17-23 depend either directly or indirectly from claim 16.

As discussed above, Wang et al. do not teach or suggest a dietary fiber composition isolated from a cereal grain containing  $\beta$ -glucan, comprising: a  $\beta$ -glucan composition having a weight average molecular weight ranging from about 50 kDa to about 250 kDa, wherein a 1% mixture by weight of said dietary fiber composition and water is stable and has a viscosity of about 1500 cps or less (*i.e.*, the dietary fiber composition of claim 1). Therefore, Wang et al. do not teach or suggest a food product that has as a component the dietary fiber composition of claim 1.

Smith, either alone or in combination with Wang et al., does not remedy the deficiencies of Wang et al. Smith extensively discusses throughout the specification that his dietary fiber products have mouthfeel properties associated with fats. See, e.g., col. 1, lines 45-50; col. 2, lines 34-39, 44-51, 52-55; col. 3, lines 44-54; col. 4, line 63 through col. 5, line 2; col. 8, lines 57-63; col. 10, lines 7-9; and col. 16, lines 23-25. The present invention, however, has minimal mouthfeel. The present invention, in particular, does not have the texture or mouthfeel attributes of a fat. Therefore, the claimed product is clearly distinguishable from the product of Smith.

Further, Smith specifically states that "care must be taken to avoid excessive starch hydrolysis in the process of the present invention due to alpha-amylase attack. If such excessive starch hydrolysis does occur, then the improvements described herein will not be realized. This excessive starch hydrolysis is avoided by taking care to limit the amount of alpha-amylase utilized in the process of the present invention." (Col. 6, lines 19-25). "Furthermore, one skilled in the art will appreciate when the alpha-amylase levels are too high by observing the failure of

the final beta-glucanase treated water-soluble dietary fiber composition to exhibit the performance improvements described herein.” (Col. 6, lines 36-40). Thus, it is critical to the process disclosed in Smith that the starch only be partially digested so that the product retains mouthfeel properties associated with fats. Thus, the process described in Smith is distinguishable from the process claimed in the present application.

Therefore, since neither Wang et al. nor Smith teach the claimed  $\beta$ -glucan having a weight average molecular weight ranging from about 50 kDa to about 250 kDa having a neutral, non-lubricious mouthfeel, even when combined, these references do not teach the claimed invention. Thus, the claims are patentable over Wang et al. in view of Smith.

Applicant respectfully asserts that this rejection under 35 U.S.C. § 103(a) should be withdrawn.

### **35 U.S.C. § 102(e) – Morgan**

The Examiner rejected claims 1-16 and 32 under 35 U.S.C. § 102(e), as being anticipated by Morgan (2003/0154974).

Claims 1-16 and 32 are described above.

35 U.S.C. § 102(e) provides that “a person shall be entitled to a patent unless . . . (e) the invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent . . .”

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Dillon*, 919 F.2d 688, 16 U.S.P.Q.2d 1897, 1908 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, “it is only necessary for the patentee to show some tangible difference between the invention and the prior art.” *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

Morgan discloses a process for extraction of  $\beta$ -glucan from cereals that add texture to a food product. For example, Morgan at ¶ 0003 states that “ $\beta$ -glucan is desirable as a food additive to impart texture (“mouth feel”) to foods,” and ¶ 0007 indicates that “low molecular weight  $\beta$ -glucan can form a gel having a beneficial textural properties for processed foods

(underline added).” Thus, the  $\beta$ -glucan generated by the Morgan process is distinguishable from the presently claimed  $\beta$ -glucan, which has a neutral, non-lubricious mouthfeel and is not a gel.

Further, the claimed invention is highly stable in water, whereas the Morgan product would not be stable because the fat has not been removed from the Morgan composition. The natural fat content of barley is greater than 2% (*see*, MacGregor and Bhatti, eds., *Barley: Chemistry and Technology* (1993) at page 202). The present specification at ¶ 0007 states that the term “highly stable in water” means “that a 1% by weight solution of the dietary fiber composition in water shows little to no precipitate, when stored overnight (16 hours) at refrigeration temperature (40°F.).” The process of the present invention removes most, if not all, of the fat from the composition, such as with a water-miscible solvent (*e.g.*, methanol, ethanol, propanol) (¶ 0071 and Examples 1-6). Because Morgan does not remove the fat from the composition, one of skill in the art would know that it would not be stable in water because fat-containing compositions are not stable in water.

Moreover, claim 15 recites that the dietary fiber composition has a fat content of about 2% or less, and claim 53 recites that the dietary fiber composition has a fat content of about 1% or less. One of skill in the art would know that because Morgan does not remove the fat from his composition, the product would be higher in fat content than the claimed values.

Also, claim 11 recites that the weight average molecular weight of the  $\beta$ -glucan composition ranges from about 120 kDa to about 170 kDa. Morgan at Table 3 states that  $\beta$ -glucan was generated with weight average molecular weight of 19k and 75k (presumably the units are Da, though they are not given) having relative viscosities of 49 and 123, respectively (presumably the units are cps, though no units are given) using a 2-enzyme process, or 194k having relative viscosity of 300 using a 1-enzyme process. Morgan does not, however, teach  $\beta$ -glucan with weight average molecular weight of about 120 kDa to about 170 kDa. Since Morgan does not, teach  $\beta$ -glucan with weight average molecular weight of about 120 kDa to about 170 kDa as recited by claim 11, this claim is not anticipated by Morgan.

Therefore, the claims are not anticipated by Morgan, and this rejection under 35 U.S.C. §102(e) should be withdrawn.

**35 U.S.C. § 103(a) – Morgan**

The Examiner rejected claims 1-16 and 32 under 35 U.S.C. § 103(a) as obvious over Morgan (2003/0154974).

Claims 1-16 and 32 are described above.

As discussed above, an objective analysis of determining obviousness involves (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, and (3) resolving the level of ordinary skill in the pertinent art. Cited documents must be considered in their entirety, and it is not permissible to pick and choose from any one document only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such document fairly suggests to one of ordinary skill in the art.

As discussed above, the pending claims are distinguishable over Morgan because Morgan discloses a textured composition, in contrast to the present invention which has a neutral mouthfeel. Further, Morgan does not remove the fat from the composition, so the Morgan product would not be stable in water, whereas the present invention is stable in water. Because Morgan does not teach all the features of the claimed invention, the claims are patentable over Morgan.

Applicant respectfully asserts that this rejection of claims 1-16 and 32 under 35 U.S.C. § 103(a) as obvious over Morgan should be withdrawn.

**35 U.S.C. § 103(a) – Morgan**

The Examiner rejected claims 17-23 under 35 U.S.C. § 103(a) as obvious over Morgan (2003/0154974).

Claims 17-23 are described above as being drawn to a dietary fiber composition incorporated into a food product.

As discussed above, the pending claims are distinguishable over Morgan because Morgan discloses a textured composition, in contrast to the present invention which has a neutral mouthfeel. Further, Morgan does not remove the fat from the composition, so the Morgan product would not be stable in water, whereas the present invention is stable in water. Because Morgan does not teach all the features of the claimed invention, the claims are patentable over Morgan. Since Morgan does not recite all the features of the present invention, claims 17-23 are

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patentable over Morgan, and Applicants respectfully request that this rejection of claims under 35 U.S.C. § 103(a) be withdrawn.

### **CONCLUSION**

The Examiner is invited to contact Applicant's Representative at the below-listed telephone number if there are any questions regarding this Response or if prosecution of this application may be assisted thereby. If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 50-3503. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extension fees to Deposit Account 50-3503.

Respectfully submitted,

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